

CLAIMS

What is claimed is:

1. A method for inducing T cell tolerance in a sample of *ex vivo* peripheral blood mononuclear cells (PBMCs) comprising adding a suppressive-inducing composition to said cells.
- 5 2. A method for treating donor cells to ameliorate graft versus host disease in a recipient patient comprising:
 - a) removing peripheral blood mononuclear cells (PBMC) from a donor;
 - b) treating said cells with a suppressive-inducing composition for a time sufficient to induce T cell tolerance; and
 - 10 c) introducing said cells to said patient.
3. A method according to claim 1 or 2 wherein said suppressive-inducing composition comprises TGF- β and IL-2.
4. A method according to claim 1 or 2 further comprising treating said donor cells with a T cell activator.
- 15 5. A method according to claim 4 wherein said T cell activator is a recipient cell.
6. A method according to claim 2 wherein said method further comprises adding said cells to donor stem cells prior to introduction into said patient.
7. A method according to claim 1 or 2 wherein said PBMCs are enriched for CD8+ cells.
8. A method according to claim 1 or 2 wherein said PBMCs are enriched for CD4+ cells.
- 20 9. A method for generating suppressor cells in a sample of *ex vivo* peripheral blood mononuclear cells (PBMCs) comprising adding a suppressive-inducing composition to said cells.
10. A method for treating donor cells to ameliorate graft versus host disease in a recipient patient comprising:
 - a) removing peripheral blood mononuclear cells (PBMC) from a donor;
 - 25 b) treating said cells with a suppressive-inducing composition for a time sufficient to generate suppressor cells; and
 - c) introducing said cells to said patient.

11. A method according to claim 9 or 10 wherein said suppressive-inducing composition comprises TGF- β .

12. A method according to claim 9 or 20 wherein said suppressive-inducing composition comprises a mixture of IL-2 and TGF- β .

13. A method according to claim 9 or 10 further comprising treating said donor cells with a T cell activator.

14. A method according to claim 13 wherein said T cell activator is a recipient cell.

15. A method according to claim 10 wherein said method further comprises adding said cells to donor stem cells prior to introduction into said patient.

16. A method according to claim 9 or 10 wherein said PBMCs are enriched for CD8+ cells.

17. A method according to claim 9 or 10 wherein said PBMCs are enriched for CD4+ cells.

18. A kit for the treatment of donor cells comprising:

- a) a cell treatment container adapted to receive cells from a donor; and
- b) at least one dose of a suppressive-inducing composition.

19. A kit for the treatment of donor cells according to claim 18 further comprising at least one dose of a T cell activator.

20. A kit according to claim 18 or 19 further comprising written instructions for the method of treating.

21. A kit according to claim 18 or 19 wherein said dose is contained within said cell treatment container.

22. A kit according to claim 18 or 19 wherein said dose is in a lyophilized form.

23. A kit according to claim 18 or 19 wherein said cell treatment container further comprises at least one reagent.

24. A kit according to claim 18 or 19 wherein said cell treatment container further comprises a sampling port to enable the removal of a fraction of said cells for analysis.

25. A kit according to claim 18 or 19 further comprising an exit port adapted to enable transport at least a portion of said cells to a recipient patient.

26. A kit according to claim 18 wherein said suppressive-inducing composition is a mixture of IL-2 and TGF- β .

5 27. A kit according to claim 19 wherein said T cell activator is a mitogen.

28. A kit according to claim 27 wherein said mitogen is staphylococcal enterotoxin B.

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